

**REMARKS****Section I – Extension of Time**

A petition for extension of time is being filed concurrently herewith.

**Section II – RCE**

In addition, a Request for Continued Examination under 37 CFR 1.114 is being filed concurrently herewith.

**Section III – Declaration under 37 CFR 1.132**

Submitted herewith is a **DECLARATION OF KRISHAN SHAH UNDER 37 CFR 1.132**, hereinafter referred to as the "Shah Declaration". This declaration is submitted in support of the patentability of the present claims.

**Section IV - Double Patenting (Provisional Rejection)**

The Examiner has issued a provisional rejection of claims 1-23 and 25-35 based on double patenting in view of applicant's co-pending application no. 10/666,288. Applicant respectfully submits that it is unknown what the scope of the claims in the co-pending application will ultimately be, and amendments in the co-pending application may obviate the objection. Applicant accordingly submits that this objection cannot be properly addressed until the disposition of the co-pending application is known. Upon allowance of one or more claims in both applications, the Applicant will add a suitable terminal disclaimer if required.

**Section V - Claim Status**

The above-identified application has been carefully reviewed in light of the Office Action mailed on October 5, 2006.

Claims 16-28 remain in this application. Claim 28 is original. Claims 17, 19, 20, 26 and 27 were previously presented and Claims 16, 18, and 21 - 25 are currently amended. Claims 1-15 and 29-35 remain withdrawn from consideration. Claims 36-39 were previously cancelled.

#### **Section VI - Claim rejection under 35 USC 112.**

The Examiner has rejected claims 23 and 25-27 due to insufficient antecedent basis for the term "said electrical parameter" in these claims. Applicant respectfully submits that the term "an electrical parameter" appears in claim 16 as previously presented and thus serves as sufficient antecedent basis for claims 25-27, which depend from independent claim 16. Amended claim 23 does not include the term "said electrical parameter". Therefore, applicant respectfully requests that this rejection of claims 23 and 25-27 be withdrawn.

#### **Section VII - Claim rejections under 35 USC 103**

The Examiner has rejected claims 16, 17, 19-22 and 28 as being unpatentable over Eggers et al. (6,032,674) (hereinafter "Eggers") in view of Shah et al. (6,565,562) (hereinafter "Shah"). In addition, claims 18, 23 and 25-27 have been rejected as being unpatentable over Eggers et al. in view of Shah et al. and further in view of Krishnan (2004/0133113) (hereinafter "Krishnan").

Krishnan discloses using a needle to pierce a hole through a septum (for example, and non-limitingly, at paragraph 0082). There is no mention nor any suggestion in Krishnan that a channel can be created through cardiac septal material by delivering radio-frequency electrical current through the cardiac septal material. Eggers discloses a device and a method for creating channels

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through the myocardium (the muscular layer located at the periphery of the heart) using radio-frequency electrical current. However, Eggers nowhere mentions that the device could be used to create a channel through cardiac septal material. In addition, Eggers does not mention that an electrode is usable both to deliver electrical current to a cardiac septal material and to obtain data about an electrical parameter of a cardiac septal material using the electrode so as to substantially assess the position of the device. Shah describes a method for creating a hole in an atrial septum by delivering radiofrequency energy using an active electrode in conjunction with a ground plate. Shah describes the active electrode as having a diameter of 0.045 cm. Shah does not describe using the active electrode to obtain data about an electrical parameter of the atrial septum.

Amended claim 16 includes the following limitations:

obtaining data about an electrical parameter of said cardiac septal material using said active electrode so as to substantially assess the position of said surgical device;

...

wherein said active electrode has a diameter of 0.04 cm or less.

Applicant respectfully submits that none of the references cited by the Examiner, alone or in combination, teach or suggest that an electrode having a diameter of about 0.04 cm or less, as presently claimed, is usable both for delivering an electrical current and for obtaining data about an electrical parameter of a cardiac septal material so as to substantially assess the position of a surgical device. The references cited by the Examiner, and/or presented by applicant, are either silent as to the specific size of an electrode usable to obtain electrograms or intracardiac ECG signals, or mention that such an electrode is larger than the claimed electrode. As mentioned hereinabove, Shah discloses an active electrode for creating a perforation having a diameter of 0.045 cm. Furthermore, Eggers mentions that an electrode having a diameter within the range of 0.05 to

3 mm (i.e. 0.005 to 0.3 cm) is usable to deliver electrical energy, but these references neither teach nor suggest using such electrodes to measure electrical signals such as electrograms, intracardiac ECGs, or any other electrical signals usable to assess the position of an electrode.

Furthermore, the applicant respectfully submits, as stated in the Shah Declaration, that using an electrode having a diameter of 0.04 cm or less to obtain electrical signals from cardiac septal material would not have been obvious to a person skilled in the art at the time the invention was conceived due to the small size of such an electrode. It is well established in the field that an ECG electrode having a larger surface area results in a higher-amplitude signal and, conversely, that an electrode having a smaller surface area results in a lower-amplitude signal (Paragraph 7 of the Shah Declaration). In addition, the electrode of the claimed invention is located adjacent the distal end of an elongated device inserted through the body of a patient, and is therefore relatively difficult to manipulate precisely. For these reasons, the relatively small size of the claimed electrode would be considered problematic for the person skilled in the art to ensure that the electrode contacts properly the cardiac septal material to obtain the electrical parameter of the cardiac septal material.

In support of the preceding statement, the Applicant respectfully submits, as mentioned in the Shah Declaration, that devices typically used to obtain electrograms or intracardiac ECGs, for example electrophysiology (EP) mapping catheters, generally have electrodes with a diameter of about 7 French, or about 2.3 mm. In view of the facts laid out in the Shah Declaration, and further in view of the arguments made herein, applicant respectfully submits that the generally accepted knowledge in the field of the invention would have led a person skilled in the art to believe that electrodes having a diameter of 0.04 cm or less would be completely unsuitable to adequately record electrical signals from cardiac septal material as claimed.


Applicant discovered the new and unexpected result that the signals obtained using the claimed electrode contain sufficient information to allow assessing the position of the electrode. As mentioned in the specification at paragraph [0059], the detection of a "distinctive change" in electrical signals between the fossa ovalis and the remainder of the atrial septum is sufficient to assess the position of the electrode. It was unexpectedly found that an electrode having a diameter of 0.04 cm provided sufficient information to detect such distinctive changes. Thus, applicant found that using an electrode having a diameter of 0.04 cm or less, which is usable to create a channel through tissue using radiofrequency electrical current, as opposed to merely ablating the tissue, is also usable to assess the position of the electrode within the heart.

Claims 18, 21, 22 and 25 have been amended in order to correct for minor typographical errors as well as to clarify applicant's invention. No new matter has been added by any amendments made in the present response.

Claims 17-28 all depend directly or indirectly from claim 16 and as such include all the limitations of this base claim. Accordingly, applicant respectfully submits that these claims distinguish over the art cited by the Examiner for the same reasons as those expressed hereinabove with respect to claim 16.

It is respectfully submitted that when the rejection of the claims is reviewed in light of applicant's arguments and the Shah Declaration, the invention should be considered patentably distinguished over the cited references. It is now believed the above application is in condition for allowance and such action would be appreciated.

Very respectfully submitted.



Louis Tessier, Reg : 45,289

Agent for the Applicant